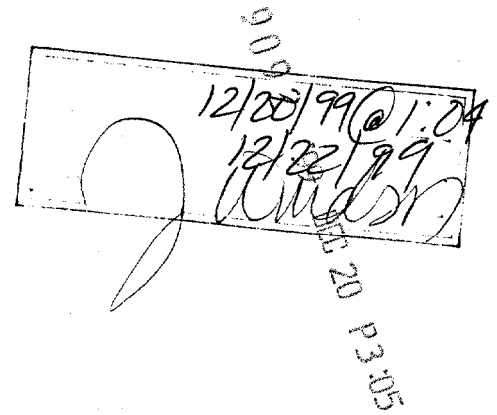


DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-5424]



Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements." The guidance is based on the report of an FDA Food Advisory Committee (FAC) Working Group that was asked to advise the agency on interpretation of the scientific standard "significant scientific agreement," which FDA applies in its review of scientific data for health claims. This action is being taken to provide guidance to industry and to comply with a recent court decision that instructed FDA to clarify the meaning of the significant scientific agreement standard.

DATES: Written comments should be submitted by *[Insert Date 60 Days After Date of Publication in the **Federal Register**]*, to ensure adequate consideration in the preparation of a revised guidance, if warranted. However, written comments may be submitted at anytime.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Comments are to be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the guidance entitled "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements" to the Office of Special Nutritionals (HFS-450), Center for **Food** Safety

and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-addressed adhesive label to assist that office in processing your request, or include a fax number to which the guidance may be sent. Alternatively, you may request a copy of the guidance by calling 202-205-4168, or you may fax your request to 202-205-5295. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Sharon A. Ross, Center for Food Safety and Applied Nutrition (HFS-450), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4168.

I. Background

SUPPLEMENTARY INFORMATION: The Nutrition Labeling and Education Act of 1990 (NLEA), which amended the Federal Food, Drug, and Cosmetic Act (the act), authorized FDA to allow food labels to carry statements that describe the relationship between a food substance and a disease or health-related condition (“health claims”) (section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B))). To ensure the scientific validity of health claims, NLEA required that FDA authorize a health claim in the labeling of conventional foods only if the agency “determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence” (section 403(r)(3)(B)(i) of the act (21 U.S.C. 343(r)(3)(B)(i))). By regulation, FDA adopted the same standard for health claims in the labeling of dietary supplements (§ 101.14(c)(2) 1 CFR 101.14(c)).

In 1996, FDA asked its FAC to convene a working group to develop a guide for preparing petitions for health claims. In response to the recent decision of the Court of Appeals for the District of Columbia Circuit in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), which required FDA to clarify the meaning of “significant scientific agreement,” the focus of the FAC Working

Group shifted to the scientific review of data for health claims and the interpretation of the significant scientific agreement standard. The working group's final report entitled "Interpretation of Significant Scientific Agreement in the Review of Health Claims" was made public during the FAC meeting of June 24 and 25, 1999. FDA concurs with the conclusions of the working group and is issuing a guidance based on the working group's final report.

This guidance represents the agency's current thinking on the meaning of the significant scientific agreement standard in section 403(r)(3) of the act (21 U.S.C. 343(r)(3)) and § 101.14(c). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

This guidance is a Level 1 guidance under FDA's good guidance practices (GGP's) (62 FR 8961, February 27, 1997). Consistent with GGP's, the agency is soliciting public comment, but is implementing the guidance immediately to promptly comply with the decision in *Pearson v. Shalala*.

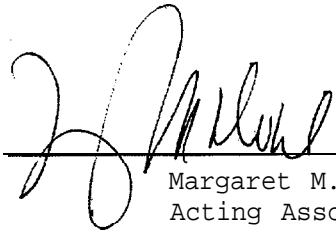
II. Comments

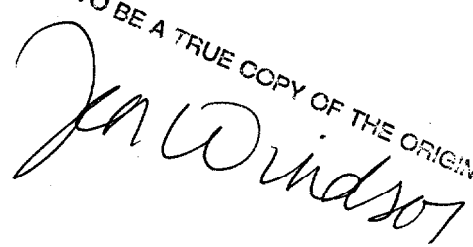
Interested persons should submit written comments on the guidance to the Dockets Management Branch (address above), by *[Insert Date 60 Days After Date of Publication in the Federal Register]*, to ensure adequate consideration in the preparation of a revised guidance, if warranted. However, written comments may be submitted at anytime. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the guidance also is available on the Internet at <http://www.cfsan.fda.gov/~dms/guidance.html#lab>.

Dated: 12-17-99
December 17, 1999


Margaret M. Dotzel
Acting Associate Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL


[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F